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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,878	03/05/2002	Terry G. Kelley	COCH-0010	6957

7590 03/01/2004

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EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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TECHNOLOGY CENTER R3700

## Office Action Summary

Application No.

10/091,878

Applicant(s)

KELLEY, TERRY G.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2 & 6.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement filed 20 August 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Three of the cited references (10, 32 and 33) are noted as being voluminous and easily obtainable by the Examiner. The Examiner does not have access to these references and they have not been considered. It is suggested that copies of only the relevant portions of these documents be submitted for consideration. It is noted that listed documents 32 and 33 appear to be the same reference.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities:

In line 3, after "material" is the limitation "patch body," which is inconsistent from the prior use of "patch or mask body." Appropriate correction is required.

### ***Claim Rejections***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

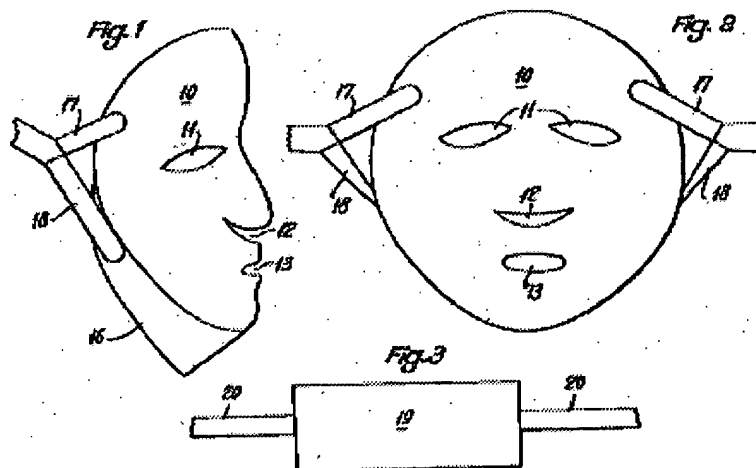
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Claims 1-13, 16, 17, 22, 25, 26, 31 and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by Meckelburg (US 3,154,070).

Regarding claim 1, Meckelburg teaches a facial or neck patch or mask for treatment of facial or neck skin aging in a mammalian subject comprising:

a flexible patch or mask body (10, 19) formed of a porous material (col. 2, lines 8-21), said patch body (10, 19) sized and dimensioned to conform to a facial or neck skin area of said subject;

attachment means (17, 18, 20) connected to the patch or mask body (10, 19) for securely, removably attaching the patch or mask (10, 19) in contact with one or more contoured facial and/or neck skin areas of the subject; at least one anti-aging effective compound (col. 1, lines 21-25; col. 4, lines 19-23) provided in chemical communication with an undersurface of the patch or mask body (10, 19) to effectuate delivery of the anti-aging compound to the contoured facial and/or neck skin area in an effective amount, and for an effective period of time to prevent or alleviate symptoms of skin aging in the facial and/or neck skin area to which the patch or mask is applied (see figures 1-3, below)(col. 1, lines 21-25; col. 4, lines 19-40).



Regarding claim 2, Meckelberg teaches a facial or neck patch or mask wherein the flexible patch or mask body (10, 19) is sized and dimensioned to conform to one or more contoured facial and/or neck skin area(s) of the subject selected from an orbital margin, nasal skin area, labial margin, mandibular, maxillary, or temporal lateral facial skin area, chin, jaw and/or neck skin area of the subject (see figures 1-3).

Regarding claim 3, Meckelberg teaches a facial or neck patch or mask wherein the facial or neck patch or mask conforms and stretches in conjunction with normal facial and neck skin movements as occur during jaw flexure, head turning, and eye opening and closure (col. 2, lines 17-40, discusses elastic construction of the device).

Regarding claim 4, Meckelberg teaches a patch or mask body (10, 19) constructed for expansion and/or elastic flexure in all directions planar to an undersurface of the patch or mask that is applied to a facial or neck skin area to be treated (col. 2, lines 17-40).

Regarding claim 5, Meckelberg teaches attachment means (17, 18, 20) selected from: a tie, elastic or other manual closure means that attaches to opposing lateral margins of the patch or mask (10, 19) and encircles a head of the subject.

Regarding claim 6, Meckelberg teaches a facial or neck patch comprising an orbital patch or mask (10, 11) sized and dimensioned to conform to an orbital margin of the subject for treatment of periorbital skin aging in the subject (see figures 1 & 2).

Regarding claim 7, Meckelberg teaches a orbital patch or mask (10) which conforms (11) to one or more portions of the orbital margin of the subject selected from a supraorbital margin, infraorbital margin, lateral orbital and/or medial orbital margin of the eye (see figures 1 & 2).

Regarding claim 8, Meckelberg teaches a patch or mask (10) comprising one or more separate or conjoined, countoured sections (11) individually shaped and dimensioned to conform to a selected portion of the orbital margin (see figures 1 & 2).

Regarding claim 9, Meckelberg teaches a orbital patch or mask (10) wherein said one or more separate or conjoined, countoured sections (11) are individually shaped and dimensioned to conform to a portion of the orbital margin selected from: a lenticular area of the supraorbital margin; a lenticular area of the infraorbital margin; a medial orbital margin; and a lateral orbital margin (see figures 1 & 2).

Regarding claim 10, Meckelberg teaches one or more separate or conjoined, countoured sections (11) are conjoined in a single patch or mask (10) having a unitary body or by interconnecting member(s) joining the individual sections in an anatomically integrated array of sections (see figures 1 & 2).

Regarding claim 11, Meckelberg teaches a facial or neck patch or mask (10) comprising a nasal skin patch or mask sized and dimensioned to conform (12) to a nasal skin surface of the subject for treatment or prevention of nasal skin aging in the subject (see figures 1 & 2).

Regarding claim 12, Meckelberg teaches a facial or neck patch or mask (10) comprising a labial skin patch or mask sized and dimensioned to conform (12) to a labial margin of the subject for treatment or prevention of perilabial skin aging in the subject (see figures 1 & 2).

Regarding claim 13, Meckelberg teaches a facial or neck patch or mask (19) comprising a neck skin patch or mask sized and dimensioned to conform to a neck skin surface of the subject for treatment or prevention of neck skin aging in the subject (see figure 3).

Regarding claim 16, Meckelberg teaches the facial or neck patch or mask (10, 19) wherein the patch or mask body, or at least an undersurface portion thereof, serves as a substrate or reservoir for receiving and retaining the anti-aging effective compound (col. 2, lines 17-40).

Regarding claim 17, Meckelberg teaches a the facial or neck patch or mask (10, 19) wherein the anti-aging effective compound is absorbed, adsorbed, or otherwise admixed with or invested in a material of the patch or mask body in direct chemical communication between the patch or mask body and the undersurface thereof through pores, fissures, perforations, and/or other communication channels provided within the patch or mask body (10, 19) or a layer thereof adjacent the undersurface (col. 2, lines 17-40).

Regarding claim 22, Meckelberg teaches a plurality of anti-aging effective compounds are applied simultaneously or coordinately with the patch or mask to yield enhanced treatment or prophylaxis of skin aging in the subject (col. 3, lines 19-23).

Regarding claim 25, Meckelberg teaches a facial or neck patch or mask (10, 19) comprising a facial mask (10) shaped and dimensioned to conform to multiple facial skin areas (see figures 1 & 2).

Regarding claim 26, Meckelberg teaches a facial mask further comprising a separate or integral, self-contained or externally charged thermal element (column 1, lines 57-60).

Regarding claim 31, Meckelberg teaches a patch or mask body (10, 19) comprised of a polymer or fiber material (col. 2, lines 7-40).

Regarding claim 32, Meckelberg teaches a method for treating facial and/or neck skin aging in a mammalian subject comprising: applying a facial or neck patch or mask (10, 19) to a

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facial and/or neck skin area(s) in the subject, wherein the patch or mask comprises a flexible patch body formed of a porous material sized and dimensioned to conform to one or more contoured facial and/or neck skin area(s) of the subject; and removably securing the patch or mask (10, 19) to the facial and/or neck skin area(s) by attachment means (17, 18, 20) connected to the patch body (10, 19), wherein the patch or mask (10, 19) delivers an anti-aging effective compound to the facial skin and/or neck skin area(s) from an undersurface of the patch or mask body after the patch or mask has been applied to yield enhanced delivery and bioavailability of the anti-aging compound to underlying facial and/or neck skin area(s) to substantially prevent or alleviate one or more symptoms of facial and/or neck skin aging therein (claim 1).

Claims 1 and 27-30 are rejected under 35 U.S.C. § 102(b) as being anticipated by De St. Cyr (US 2,210,618).

Regarding claim 1, De St. Cyr teaches a facial or neck patch or mask for treatment of facial or neck skin aging in a mammalian subject comprising:

a flexible patch or mask body (1) formed of a porous material (11), said patch body (1) sized and dimensioned to conform to a facial or neck skin area of said subject;

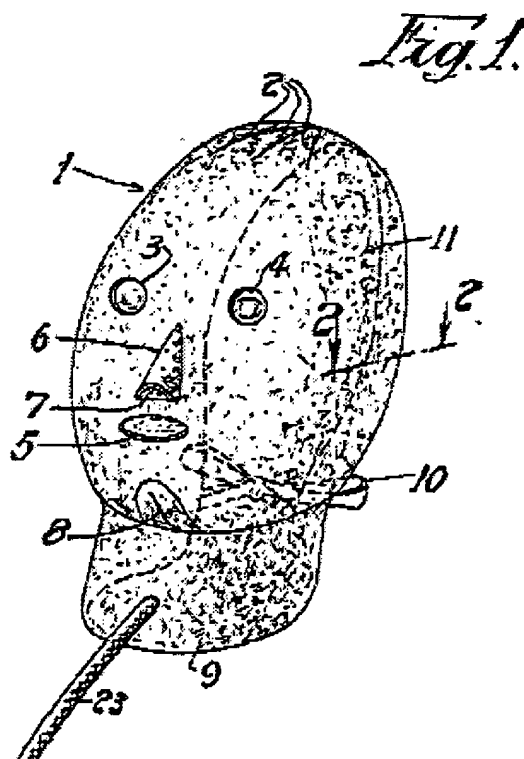
attachment means (10) connected to the patch or mask body (1) for securely, removably attaching the patch or mask (1) in contact with one or more contoured facial and/or neck skin areas of the subject; at least one anti-aging effective compound (heated paraffin wax) provided in chemical communication with an undersurface of the patch or mask body (1) to effectuate delivery of the anti-aging compound to the contoured facial and/or neck skin area in an effective amount, and for an effective period of time to prevent or alleviate symptoms of skin aging in the facial and/or neck skin area to which the patch or mask (1) is applied (see Fig. 1, below).



Regarding claim 27, De St. Cyr teaches a facial or neck patch or mask (1) wherein the thermal element is a heating element (col. 2, lines 29-44) to facilitate delivery and activity of the anti-aging effective compound by increasing the temperature at a target skin area.

Regarding claim 28, De St. Cyr teaches a facial or neck patch or mask wherein the thermal element is a thermal gel (melted wax) that can function as a heating and/or cooling element.

Regarding claim 29, De St, Cyr teaches a facial or neck patch or mask of claim wherein the thermal element is permanently or removably enclosed within a pocket or cavity attached to or surrounded by the patch or mask body (col. 2, lines 29-44).



Regarding claim 30, De St. Cyr teaches a facial or neck patch or mask of wherein the anti-aging effective compound (wax) is formulated with a polymeric delivery vehicle, hydrogel, or biodegradable polymer or matrix.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Korol (US 4,747,845).

Meckelberg expressly teaches the claimed invention except for delayed release of the compound.

Korol teaches a synthetic resin matrix for extended release of medicaments which can be applied via an external skin dressing (abstract, figure 1).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the drug release mechanism of Korol to the mask or patch of Meckelberg in order to provide a means of controlling the release rate of its active compounds.

Regarding claim 15, Meckelberg teaches a facial or neck patch or mask of claim wherein the patch or mask effectively delivers the anti aging effective compound to achieve an effective concentration anti aging effective compound to reduce or prevent symptoms of facial and/or neck skin aging caused by degeneration of the microvascular system (col. 2, lines 38-40).

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Regarding claim 24, any time released compound provided by the combination of Meckelberg and Korol would provide controlled, time-release delivery of one or more compound(s) for a prolonged delivery time period selected from: 1-4 hours; 4-8 hours; or more than 8 hours.

Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Lorenz (US 5,306,504 A).

Meckelberg teaches the claimed invention except for a bioadhesive.

Lorenz teaches a skin adhesive hydrogel (abstract).

At the time of the invention, it would have been obvious to combine the skin adhesive of Lorenz with the mask or patch of Meckelberg in order to provide a means of better securing the mask or patch to a patient while minimizing skin irritation.

Claims 20, 21 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Kaddurah-Daouk (US 6,242,491 B1).

Meckelberg teaches the claimed invention except for the specific anti-aging compound.

Kaddurah-Daouk teaches the use of Coenzyme Q<sub>10</sub> or vitamin E as an anti-aging agent (col. 15, lines 7-11).

At the time of the invention, it would have been obvious to select Coenzyme Q<sub>10</sub> or vitamin E as the anti aging agent for the mask or patch of Meckelberg in order to provide a effective skin preserving effect.


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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (703) 605-1184. The examiner can normally be reached Monday-Friday.

In the event the examiner is not available, the examiner's supervisor, John Calvert may be reached at phone number (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 746-3380 for informal communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-0858.

  
Michael Bogart  
20 February 2004

  
JOHN CALVERT  
SUPERVISOR PATENT EXAMINER  
TECHNOLOGY CENTER 3700



## Form PTO-1449 Modified

Docket No.  
**COCH-0010**Serial No.  
**10/091,878**List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)Applicant  
**Terry G. Kelley**U.S. Department of Commerce  
Patent and Trademark OfficeFiling Date  
**March 5, 2002**Group  
**3765****OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

M6B	1	Black, H.S., "Potential involvement of free radical reactions in ultraviolet light-mediated cutaneous damage," <i>Photochem. Photobiol.</i> , <b>1987</b> , 46(2), 213-221
M6B	2	Chonn, A., et al., "Recent advances in liposomal drug-delivery systems," <i>Curr. Opin. Biotechnol.</i> , <b>1995</b> , 6, 698-708
M6B	3	Cohen, S., et al., "Controlled delivery systems for proteins based on poly(lactic/glycolic acid) microspheres," <i>Pharm. Res.</i> , <b>1991</b> , 8(6), 713-720
M6B	4	Emerit, I., "Free radicals and aging of the skin," <i>Birkhäuser Verlag</i> , Emerit, I., et al. (Eds.), <b>1992</b> , 328-341
M6B	5	Giacomoni, P.U., et al., "Aging of human skin: Review of a mechanistic model and first experimental data," <i>IUBMB Life</i> , <b>2000</b> , 49, 259-263
M6B	6	Gregoriadis, G., "Engineering liposomes for drug delivery: progress and problems," <i>TIBTECH</i> , December <b>1995</b> , 13, 527-537
M6B	7	Heller, J., "Use of poly(ortho esters) and polyanhydrides in the development of peptide and protein delivery systems," <i>Formulation and Delivery of Proteins and Peptides</i> , Cleland, J.L., et al. (Eds.), ACS Symposium Series 567, Washington, DC, <b>1994</b> , 292-305
M6B	8	Henschen, A., et al., "Fibrinogen, fibrin and factor XIII," Chapter 7, <i>Blood Coagulation</i> , Zwaal, et al. (Eds.), Elsevier, Amsterdam, <b>1986</b> , 171-241
M6B	9	Hirai, S., et al., "Mechanisms for the enhancement of the nasal absorption of insulin by surfactants," <i>Intl. J. Pharmaceutics</i> , <b>1981</b> , 9, 173-184
*	10	Ikinci, et al., <i>Advances in Chitin Science, Vol. 4</i> , Peter, et al. (Eds.), University of Potsdam, in press

EXAMINER

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\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner

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M6B	11	Illum, L., et al., "Chitosan as a novel nasal delivery system for peptide drugs," <i>Pharm. Res.</i> , 1994, 11(8), 1186-1189
M6B	12	Illum, L., "Chitosan and its use as a pharmaceutical excipient," <i>Pharm. Res.</i> , 1998, 15(9), 1326-1331
M6B	13	Jackson, M.R., "Tissue sealants: current status, future potential," <i>Nat. Med.</i> , 1996, 2(5), 637-638
M6B	14	Kajihara, J., et al., "Increased stability of PEG-PPG conjugated human urokinase against autolysis," <i>Biosci. Biotechnol. Biochem.</i> , 1997, 61(1), 197-198
M6B	15	Kas, H.S., "Chitosan: properties, preparations and applications to microparticulate systems," <i>J. Microencapsulation</i> , 1997, 14(6), 689-711
M6B	16	Kotze, A.F., et al., "chitosans for enhanced delivery of therapeutic peptides across intestinal epithelia: in vitro evaluation in Caco-2 cell monolayers," <i>Int. J. Pharm.</i> , 1997, 159, 243-253
M6B	17	Kronick, P.L., "Complexes of steroid drugs with polypropylene glycol: further observations," <i>Pharmacol. Res. Commun.</i> , 1978, 10(3), 257-259
M6B	18	Lasic, D.D., "Novel applications of liposomes," <i>TIBTECH</i> , July 1998, 16, 307-321
M6B	19	Lehr, C., et al., "Effects of the mucoadhesive polymer polycarbophil on the intestinal absorption of a peptide drug in the rat," <i>J. Pharm. Pharmacol.</i> , 1992, 44, 402-407
M6B	20	Lehr, C.M., "From sticky stuff to sweet receptors - achievements, limits and novel approaches to bioadhesion," <i>Eur. J. Drug Metab. Pharmacokinetics</i> , 1996, 21(2), 139-148

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<i>MB</i>	21	Mehta, R.C., et al., "Biodegradable microspheres as depot system for parenteral delivery of peptide drugs," <i>J. Control. Release</i> , <b>1994</b> , 29, 375-384
<i>MB</i>	22	Miyazaki, S., et al., "Chitosan and sodium alginate based bioadhesive tablets for intraoral drug delivery," <i>Biol. Pharm. Bull.</i> , May <b>1994</b> , 17(5), 745-747
<i>MB</i>	23	Muranishi, S., "Modification of intestinal absorption of drugs by lipoidal adjuvants," <i>Pharm. Res.</i> , <b>1985</b> , 2, 108-118
<i>MB</i>	24	Muranishi, S., "Absorption enhancers," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , <b>1990</b> , 7(1), 1-33
<i>MB</i>	25	Muzzarelli, R., et al., "Reconstruction of parodontal tissue with chitosan," <i>Biomaterials</i> , November <b>1989</b> , 10, 598-603
<i>MB</i>	26	Needleman, I.G., et al., "An investigation of bioadhesion for periodontal and oral mucosal drug delivery," <i>J. Clin. Periodontol.</i> , <b>1997</b> , 24, 394-400
<i>MB</i>	27	Needleman, I.G., et al., "characterisation of bioadhesives for periodontal and oral mucosal drug delivery," <i>J. Clin. Periodontol.</i> , <b>1998</b> , 25, 74-82
<i>MB</i>	28	Olsen, R., et al., "Biomedical applications of chitin and its derivatives," <i>Chitin and Chitosan-sources, Chemistry, Biochemistry, Physical Properties and Applications</i> , Skjak-Braek, G., et al. (Eds.), Elsevier, London, <b>1988</b> , 813-828
<i>MB</i>	29	Park, H., et al., "Physico-chemical properties of water insoluble polymers important to mucin/epithelial adhesion," <i>J. Control. Release</i> , <b>1985</b> , 2, 47-57
<i>MB</i>	30	Robinson, J.R., "Bioadhesive polymers as therapeutic agents and carriers of therapeutic agents for the eye, mouth and vagina," <i>Proc. Intern. Symp. Control. Rel. Bioact. Mater.</i> , <b>1991</b> , 18, page 75

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

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*	32	Rompp's Chemical Dictionary, <i>Georg Thieme Verlag Stuttgart</i> , New York, 9 <sup>th</sup> Ed.
*	33	Rompp's Chemical Dictionary, <i>Georg Thieme Verlag Stuttgart</i> , New York, 9 <sup>th</sup> Ed.
MBB	34	Salzman, R., et al., "Intranasal aerosolized insulin," <i>New Eng. J. Med.</i> , April 25, <b>1985</b> , 1078-1084
MBB	35	Schipper, N.G.M., et al., "Chitosans as absorption enhancers for poorly absorbable drugs 2: mechanism of absorption enhancement," <i>Pharm. Res.</i> , <b>1997</b> , 14, 23-29
MBB	36	Senderoff, R.I., et al., "Fibrin based drug delivery systems," <i>J. Parenter. Sci. Technol.</i> , January-February <b>1991</b> , 45(1), 2-6
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MBB	38	Senel, S., et al., "Chitosan films and hydrogels of chlorhexidine gluconate for oral mucosal delivery," <i>Int. J. Pharm.</i> , <b>2000</b> , 193, 197-203
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\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner

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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>COCH-0010</b>	Serial No. <b>10/091,878</b>
		Applicant <b>Terry G. Kelley</b>	
		Filing Date <b>March 5, 2002</b>	Group <b>3765</b>
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## Form PTO-1449 Modified

Docket No.  
**COCH-0010**Serial No.  
**10/091,878**List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)Applicant  
**Terry G. Kelley**U.S. Department of Commerce  
Patent and Trademark OfficeFiling Date  
**March 5, 2002**Group  
**3765**

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<b>Notice of References Cited</b>	Application/Control No. 10/091,878	Applicant(s)/Patent Under Reexamination KELLEY, TERRY G.	
	Examiner Michael G. Bogart	Art Unit 3761	Page 1 of 1

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	C	US-			
	D	US-			
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	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

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	O					
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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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**NOTICE OF OFFICE PLAN TO CEASE SUPPLYING COPIES OF CITED U.S. PATENT  
REFERENCES WITH OFFICE ACTIONS, AND PILOT TO EVALUATE THE  
ALTERNATIVE OF PROVIDING ELECTRONIC ACCESS TO SUCH U.S. PATENT  
REFERENCES**

**Summary**

The United States Patent and Trademark Office (Office or USPTO) plans in the near future to: (1) cease mailing copies of U.S. patents and U.S. patent application publications (US patent references) with Office actions except for citations made during the international stage of an international application under the Patent Cooperation Treaty and those made during reexamination proceedings; and (2) provide electronic access to, with convenient downloading capability of, the US patent references cited in an Office action via the Office's private Patent Application Information Retrieval (PAIR) system which has a new feature called "E-Patent Reference." Before ceasing to provide copies of U.S. patent references with Office actions, the Office shall test the feasibility of the E-Patent Reference feature by conducting a two-month pilot project starting with Office actions mailed after December 1, 2003. The Office shall evaluate the pilot project and publish the results in a notice which will be posted on the Office's web site ([www.USPTO.gov](http://www.USPTO.gov)) and in the Patent Official Gazette (O.G.). In order to use the new E-Patent Reference feature during the pilot period, or when the Office ceases to send copies of U.S. patent references with Office actions, the applicant must: (1) obtain a digital certificate from the Office; (2) obtain a customer number from the Office, and (3) properly associate applications with the customer number. The pilot project does not involve or affect the current Office practice of supplying paper copies of foreign patent documents and non-patent literature with Office actions. Paper copies of references will continue to be provided by the USPTO for searches and written opinions prepared by the USPTO for international applications during the international stage and for reexamination proceedings.

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**Description of Pilot Project to Provide Electronic Access to Cited U.S. Patent  
References**

On December 1, 2003, the Office will make available a new feature, E-Patent Reference, in the Office's private PAIR system, to allow more convenient downloading of U.S. patents and U.S. patent application publications. The new feature will allow an authorized user of private PAIR to download some or all of the U.S. patents and U.S. patent application publications cited by an examiner on form PTO-892 in Office actions, as well as U.S. patents and U.S. patent application publications submitted by applicants on form PTO/SB08 (1449) as part of an IDS. The retrieval of some or all of the documents may be performed in one downloading step with the documents encoded as Adobe Portable Document format (.pdf) files, which is an improvement over the current page-by-page retrieval capability from other USPTO systems.

## **Steps to Use the New E-Patent Reference Feature During the Pilot Project and Thereafter**

Access to private PAIR is required to utilize E-Patent Reference. If you don't already have access to private PAIR, the Office urges practitioners, and applicants not represented by a practitioner, to take advantage of the transition period to obtain a no-cost USPTO Public Key Infrastructure (PKI) digital certificate, obtain a USPTO customer number, associate all of their pending and new application filings with their customer number, install no-cost software (supplied by the Office) required to access private PAIR and E-Patent Reference feature, and make appropriate arrangements for Internet access. The full instructions for obtaining a PKI digital certificate are available at the Office's Electronic Business Center (EBC) web page at: <http://www.uspto.gov/ebc/downloads.html>. Note that a notarized signature will be required to obtain a digital certificate.

To get a Customer Number, download and complete the Customer Number Request form, PTO-SB125, at: <http://www.uspto.gov/web/forms/sb0125.pdf>. The completed form can then be transmitted by facsimile to the Electronic Business Center at (703) 308-2840, or mailed to the address on the form. If you are a registered attorney or patent agent, then your registration number must be associated with your customer number. This is accomplished by adding your registration number to the Customer Number Request form. A description of associating a customer number with an application is described at the EBC web page at: [http://www.uspto.gov/ebc/registration\\_pair.html](http://www.uspto.gov/ebc/registration_pair.html).

The E-Patent Reference feature will be accessed using a new button on the private PAIR screen. Ordinarily all of the cited U.S. patent and U.S. patent application publication references will be available over the Internet using the Office's new E-Patent Reference feature. The size of the references to be downloaded will be displayed by E-Patent Reference so the download time can be estimated. Applicants and registered practitioners can select to download all of the references or any combination of cited references. Selected references will be downloaded as complete documents as Adobe Portable Document Format (.pdf) files. For a limited period of time, the USPTO will include a copy of this notice with Office actions to encourage applicants to use this new feature and, if needed, to take the steps outlined above in order to be able to utilize this new feature during the pilot and thereafter.

During the two-month pilot, the Office will evaluate the stability and capacity of the E-Patent Reference feature to reliably provide electronic access to cited U.S. patent and U.S. patent application publication references. While copies of U.S. patent and U.S. patent application publication references cited by examiners will continue to be mailed with Office actions during the pilot project, applicants are encouraged to use the private PAIR and the E-Patent Reference feature to electronically access and download cited U.S. patent and U.S. patent application publication references so the Office will be able to objectively evaluate its performance. The public is encouraged to submit comments to the Office on the usability and performance of the E-Patent Reference feature during the pilot. Further, during the pilot period registered practitioners, and applicants not represented by a practitioner, are encouraged to experiment with the feature, develop a proficiency in using the feature, and establish new internal processes for using the new access to the cited U.S. patents and U.S. patent application publications to prepare for the anticipated cessation of the current Office practice of supplying copies of such cited

references. The Office plans to continue to provide access to the E-Patent Reference feature during its evaluation of the pilot.

### Comments

Comments concerning the E-Patent Reference feature should be in writing and directed to the Electronic Business Center (EBC) at the USPTO by electronic mail at [eReference@uspto.gov](mailto:eReference@uspto.gov) or by facsimile to (703) 308-2840. Comments will be posted and made available for public inspection. To ensure that comments are considered in the evaluation of the pilot project, comments should be submitted in writing by January 15, 2004.

Comments with respect to specific applications should be sent to the Technology Centers' customer service centers. Comments concerning digital certificates, customer numbers, and associating customer numbers with applications should be sent to the Electronic Business Center (EBC) at the USPTO by facsimile at (703) 308-2840 or by e-mail at [EBC@uspto.gov](mailto:EBC@uspto.gov).

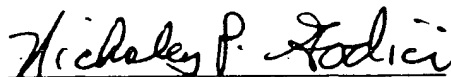
### Implementation after Pilot

After the pilot, its evaluation, and publication of a subsequent notice as indicated above, the Office expects to implement its plan to cease mailing paper copies of U.S. patent references cited during examination of non provisional applications on or after February 2, 2004; although copies of cited foreign patent documents, as well as non-patent literature, will still be mailed to the applicant until such time as substantially all applications have been scanned into IFW.

### For Further Information Contact

Technical information on the operation of the IFW system can be found on the USPTO website at <http://www.uspto.gov/web/patents/ifw/index.html>. Comments concerning the E-Patent Reference feature and questions concerning the operation of the PAIR system should be directed to the EBC at the USPTO at (866) 217-9197. The EBC may also be contacted by facsimile at (703) 308-2840 or by e-mail at [EBC@uspto.gov](mailto:EBC@uspto.gov).

Date. 12/1/03



Nicholas P. Godici  
Commissioner for Patents



US 20040024373A1

(19) **United States**(12) **Patent Application Publication** (10) Pub. No.: US 2004/0024373 A1

Ioffe et al.

(43) Pub. Date:

Feb. 5, 2004

(54) **METHOD AND DEVICE FOR CORRECTING  
OR REDUCING THE FORMATION OF  
FACIAL LINES**

(52) U.S. Cl. .... 604/303

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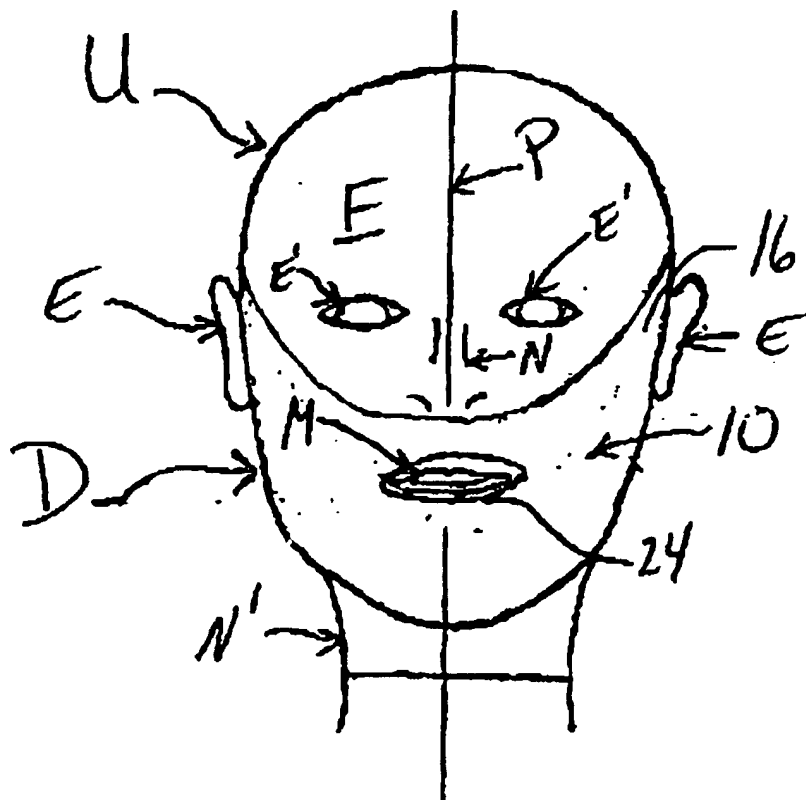
(73) Assignee: Anna Chernyakhovsky

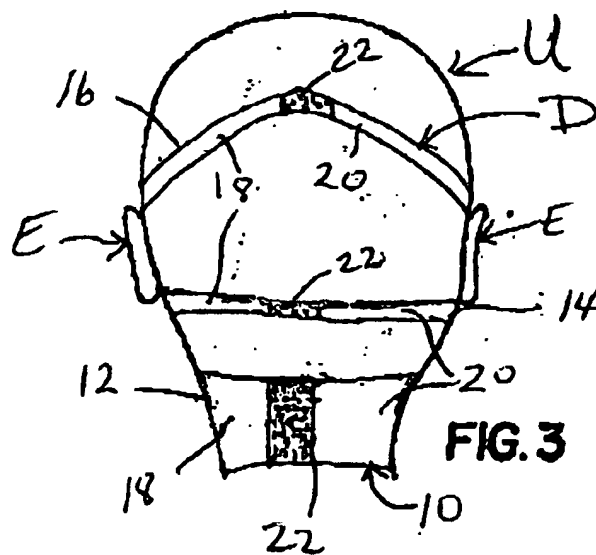
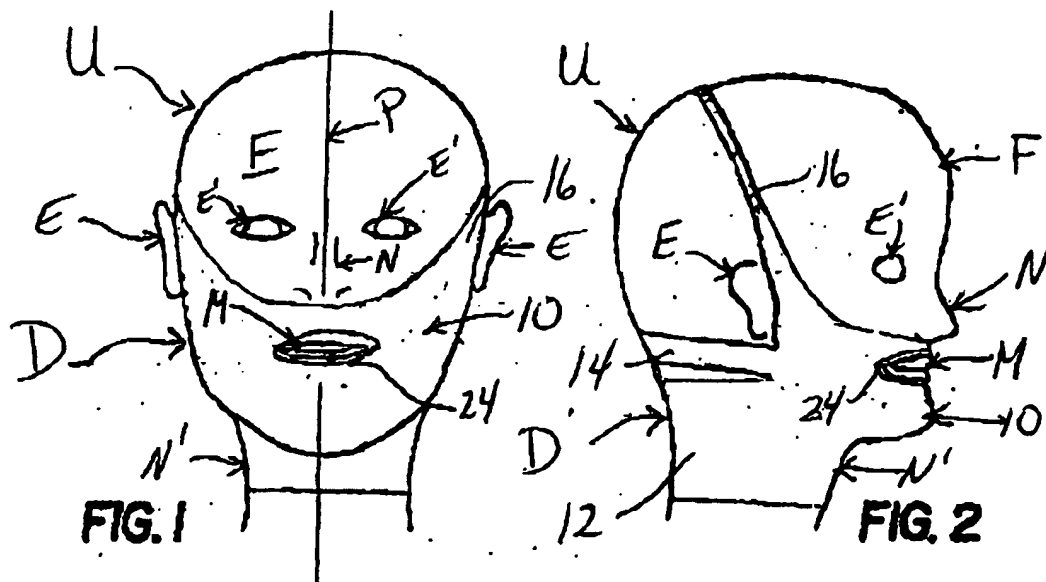
(21) Appl. No.: 10/397,828

(22) Filed: Mar. 27, 2003

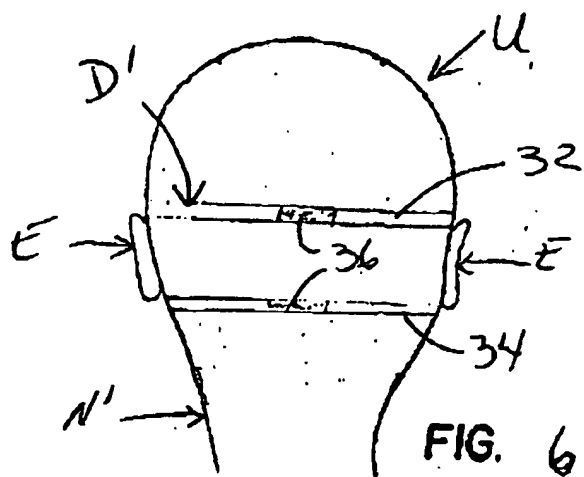
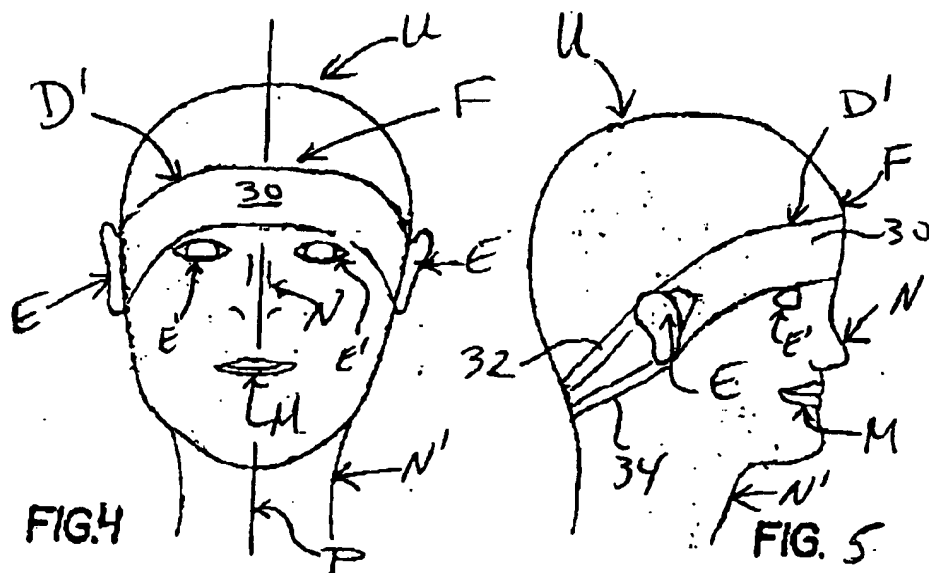
**Related U.S. Application Data**(63) Continuation of application No. 09/410,078, filed on  
Oct. 1, 1999, now abandoned.**Publication Classification**(51) Int. Cl.<sup>7</sup> ..... A61H 33/04(57) **ABSTRACT**

A method for reducing the formation of lines on the skin of a person's face and neck (and/or at least partly removing such lines) comprises applying pressure on the skin at locations where a reduction in the formation of lines (or a reduction of lines) is desired with this pressure being sufficient for at least partly impeding the development of these lines by causing the person in time to diminish his/her formation of facial expressions which cause the skin to wrinkle. If the pressure is applied for a prolonged period of time, biofeedback between the brain, muscles and skin subconsciously cause the person to reduce making such facial expressions. The device is a compression and face stabilising device which comprises a mask and/or one or more bands adapted to be positioned on the skin at the aforementioned locations, and an attachment mechanism to secure the mask to the head and/or neck of the person and which is adapted to apply sufficient pressure at such locations for at least partly impeding the development of lines thereat.











## METHOD AND DEVICE FOR CORRECTING OR REDUCING THE FORMATION OF FACIAL LINES

### CRISS-REFERENCE

[0001] This Application is a Continuation of U.S. Ser. No. 09/410,078 filed on Oct. 1, 1999, pending.

### BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to systems for improving facial aesthetics and, more particularly, for at least partly removing or reducing the formation of ageing lines on the face.

[0004] 2. Description of the Prior Art

[0005] With the ageing process, the skin loses its elasticity and cannot keep its original connection with the body's muscles. Therefore, when muscles repetitively contract to define different facial expressions, the associated skin contracts as well, but does not exactly return to its original position and shape thereby gradually creating fine lines and wrinkles.

[0006] Furthermore, during sleep, the muscles relax, skin sags down due to the forces of gravity and due to pressure exerted on the face by the bed and pillow. Consequently, continual use of the same sleeping position creates fine lines and wrinkles as a result of the fact that, with age, the skin loses its ability to bounce back after the sleep.

[0007] To try to maintain a youthful looking skin, various products, such as creams, have been developed which allegedly remove facial lines and/or prevent, or at least delay, the formation thereof.

[0008] U.S. Pat. No. 4,694,823 issued on Sep. 22, 1987 to Young discloses an apparatus for supporting chin, neck and facial tissue during sleep and including a neck-embracing lower attachment portion and an over-the-head criss-cross attachment portion for securely anchoring tissue engaging support portions to the lower chin and posterior jaw portions such as to provide uniform lifting on all of the engaged skin and neck areas to prevent and remove neck and facial sagging and wrinkling of the skin.

[0009] U.S. Pat. No. 4,934,357 issued on Jun. 19, 1990 to Frantzich et al. discloses a jaw support bandage for providing support to the jaw of a patient, for instance following oral surgery, or the like

[0010] U.S. Pat. No. 4,190,054 issued on Feb. 26, 1980 to Brennan discloses an elastic therapeutic bandage which is attachable to a body part for holding the flesh of the body part firmly in place and which comprises a flexible fluid retaining envelope that acts as a hot or cold pack.

[0011] U.S. Pat. No. 5,782,790 issued on Jul. 21, 1998 to Allen discloses a flexible compression and stabilizing orthotic made of a stretchable material and which is applied to a person afflicted with a neurological disorder, autism, proprioceptive and sensory deficits, or hypersensitivity.

[0012] U.S. Pat. No. 5,031,609 issued on Jul. 16, 1991 to Fye discloses a postoperative compression bandage for the head.

### SUMMARY OF THE INVENTION

[0013] It is therefore an aim of the present invention to provide a new system for at least partly removing or reducing the formation of ageing lines on the face.

[0014] It is also an aim of the present invention to provide a device as well as a method for at least partly removing or reducing the formation of ageing lines on the face.

[0015] Therefore, in accordance with the present invention, there is provided a method for reducing the formation of lines on the skin of a person, comprising applying pressure on the skin at locations where a reduction in said formation of lines is desired, said pressure being sufficient for at least partly impeding the development of said lines.

[0016] Also in accordance with the present invention, there is provided a device for reducing the formation of lines on the skin of a person, comprising mask means adapted to be positioned on the skin at locations where a reduction in the formation of lines is desired, and an attachment mechanism to secure said mask means to the head and/or neck of the person and being adapted to apply sufficient pressure at said locations for at least partly impeding the development of lines thereat.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Having thus generally described the nature of the invention, reference will now be made to the accompanying drawings, showing by way of illustration a preferred embodiment thereof, and in which;

[0018] FIG. 1 is a front elevational view of a device for at least partly removing or reducing the formation of lines, e.g. expression and/or sleep related lines, on the face in accordance with the present invention and shown in position on a user's face;

[0019] FIG. 2 is a side elevational view of the device and user of FIG. 1;

[0020] FIG. 3 is a rear elevational view of the device and user of FIG. 1;

[0021] FIG. 4 is a front elevational view of a device for at least partly removing or reducing the formation of lines, e.g. expression and/or sleep related lines, on the face in accordance with a second embodiment of the present invention and shown in position on a user's face;

[0022] FIG. 5 is a side elevational view of the device and user of FIG. 4;

[0023] FIG. 6 is a rear elevational view of the device and user of FIG. 4; and

[0024] FIG. 7 is a front elevational view of a human's face showing ageing lines on the prone areas thereof.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0025] In accordance with the present invention, FIGS. 1 to 3 illustrate a first embodiment of a device D, shown positioned on a face of a user U, for at least partly removing or reducing the formation of facial expression lines, sleep related lines, sagging skin, etc., and which may be used by men and women alike. The device D is designed to counteract gravity forces, to provide sensory input to the brain, to

create face shape awareness to the user U and keep the shape of the face substantially in its original form, i.e. similar to the shape of the face at one's youth. The device D prevents the skin from sagging during sleep, whereby no fine lines or wrinkles can appear.

[0026] The device D comprises a mask 10 adapted to cover the lower portion of the face, i.e. generally from below a nose N of the user U, and a neck N' of the user U, and also comprises first, second and third straps 12, 14 and 16, respectively, to hold the mask 10 against the lower face and neck N' of the user U. The first strap 12 surrounds the neck N' (i.e. at the nape), with the second strap 14 extending around a lower portion of the user's head and slightly above the first strap 12, whereas the third strap 16 extends just in front of ears E of the user U and atop an upper rear portion of the user's head. Each of the first, second and third straps 12, 14 and 16 includes a pair of strap sections 18 and 20 extending from opposed sides of the mask 10, generally symmetrically about a vertical plane P, and joining together behind the user's head and neck, for instance with Velcro™ strips 22. The mask 10 defines an opening 24 for the user's mouth M.

[0027] The device D may be made of a light, multidirectional stretchable, hygienic and comfortable material which does not alter or impede facial and neck blood circulation and allows the skin to breathe. The device D may also be made of a material having similar characteristics as above but which is not stretchable. The device D does not prevent the user U from using cosmetics and facial creams.

[0028] The device D operates to prevent or reduce the formation of lines on the face with dual action, that is as a result of the compression forces exerted on the skin by the actual physiological wearing of the device D and also the device D subconsciously stops the user U from frowning or making other facial expressions that would otherwise create lines and wrinkles. Indeed, during the active day or when the user U is sleeping, and without actual knowledge and special effort on the part of the user U, the brain, using biofeedback mechanisms, initiated by sensory input from the device D trains the user U away from the "bad" habits of making certain facial expressions which, when repeated sufficiently, ultimately create wrinkles.

[0029] The device D creates biofeedback between the user's skin, muscles and brain, to subconsciously control the formation of human behaviours and thereby assist in eliminating or reducing the formation of facial lines or wrinkles such as to impede early ageing of the user's U face.

[0030] Therefore, a method in accordance with the present invention provides sensory input and face shape awareness to the user U to stimulate the biofeedback between the brain, the muscles and the skin to prevent and correct facial fine lines and wrinkles. This is essentially achieved, for instance, by applying the present flexible compression and face stabilizing device D to the face of the user U so as not to produce lines of pull on the face but rather allow for complete freedom of neck and head movements and provide sensory input through a compression load to portion(s) of the face of the user U covered by parts of the device D, such as the mask 10 thereof.

[0031] The present device D and method associated therewith thus prevent or reduce the formation of sleep lines, fine

lines and wrinkles on the face and neck of the user U, or reduce the depth thereof or eliminate previously formed such lines and wrinkles, by providing a compression and stabilising effect on the face and neck.

[0032] The areas of the face which are to be "treated" dictate the shape of the device. Indeed, the device D of FIGS. 1 to 3 constitutes a partial face-neck mask for lower face and neck area applications other devices may have masks for different applications, such as partial face, full face and full neck-face applications.

[0033] The device can thus be designed to cover one or more of the chin, neck, eye area, leaps, forehead, cheeks, etc.

[0034] FIGS. 4 to 6 illustrate a variant device D' intended for the forehead F of the user U and comprising a mask in the form of a band 30 extending along the forehead F and held in place by upper and lower straps 32 and 34, respectively, each having, for instance, a pair of strap sections attachable together with Velcro™ strips 36 (i.e. with a construction similar to that of the straps 12 to 16 of the device D of FIGS. 1 to 3). It is readily understood that other variants or constructions of the device can be made to cover various areas of the face and/or neck of the user U.

[0035] Also, the strap sections of the straps 12, 14, 16, 32 and 34 could be connectable together with attachment systems other than the Velcro™ strips 22 and 36. The straps 12, 14, 16, 32 and 34 could each be made in a unitary construction (as opposed to having two strap sections); in such a case, the straps 12, 14, 16, 32 and 34 could be made of an elastic material.

[0036] FIG. 7 shows the user U without any device thereon for illustrating typical areas of the face and neck where the device and method of the present invention may be applied as being prone to lines and wrinkles, e.g. the forehead F, the neck N, areas surrounding the mouth M, and areas around the eyes E'.

We claim:

1. A method for reducing the formation of lines on the skin of a person, comprising applying pressure on the skin at locations where a reduction in said formation of lines is desired, said pressure being sufficient for at least partly impeding the development of said lines.

2. A method as defined in claim 1, wherein said pressure is sufficient to at least partly impede the formation of facial expressions which cause said skin to wrinkle.

3. A method as defined in claim 2, wherein said pressure is applied for a sufficient amount of time such that biofeedback between the brain, muscles and skin subconsciously cause the person to reduce making said facial expressions.

4. A method as defined in claim 3, wherein said pressure is applied by way of a compression and face stabilising device which provides sensory input through a compression load on a portion of the face covered by said device.

5. A method as defined in claim 4, wherein said device prevents said skin from sagging during sleep thereby reducing said formation of lines during sleep.

6. A method as defined in claim 4, wherein said device smoothes out fine lines and wrinkles.

7. A method as defined in claim 4, wherein the brain using biofeedback mechanisms initiated by said sensory input from said device trains the person away from making said facial expressions.

8. A method as defined in claim 4, wherein said device is made at least at said locations of a light, breathable material to allow for freedom of neck and head movements.

9. A method as defined in claim 3, wherein said pressure is applied for at least one of: preventing sleep lines on said face, correcting fine lines and/or wrinkles, and preventing fine lines and/or wrinkles.

10. A method as defined in claim 4, wherein said device covers at least one of: a chin, a neck, eye-bordering areas, leaps, a forehead and cheeks.

11. A method as defined in claim 3, wherein said pressure results in at least one of: decrease in depth of lines and/or wrinkles, disappearance of facial and/or neck lines, and disappearance of facial and/or neck wrinkles.

12. A method as defined in claim 3, further including applying an anti-wrinkling cream on said skin.

13. A device for reducing the formation of lines on the skin of a person, comprising mask means adapted to be positioned on the skin at locations where a reduction in the formation of lines is desired, and an attachment mechanism to secure said mask means to the head and/or neck of the person and being adapted to apply sufficient pressure at said locations for at least partly impeding the development of lines thereat.

14. A device as defined in claim 13, wherein said attachment mechanism is adapted to cause said mask means to provide sufficient pressure to at least partly impede the formation of facial expressions, at said locations, which cause said skin to wrinkle.

15. A device as defined in claim 14, wherein said mask means comprise a compression and face stabilising means

which provides sensory input through a compression load on a portion of the face covered by said mask means.

16. A device as defined in claim 14, wherein at least said mask means is made of a light, breathable material that allows for freedom of neck and head movements.

17. A device as defined in claim 14, wherein said mask means is adapted for being applied on at least one of: a chin, a neck, eye bordering areas, leaps, a forehead and cheeks.

18. A device as defined in claim 14, wherein said attachment mechanism comprises at least one strap extending from said mask means.

19. A device as defined in claim 18, wherein each said strap comprises a pair of strap sections connected at first ends thereof to said mask means and being detachably connectable together at second ends thereof for holding said mask means in position on said locations.

20. A device as defined in claim 19, wherein said second ends are provided with co-operating hook-and-loop strips.

21. A device as defined in claim 13, wherein said mask means comprises at least one of a band, a partial face mask, a full face mask, a partial face-neck mask, and a full face-neck mask.

22. A device as defined in claim 16, wherein at least said mask means is made of one of a multidirectional stretchable material and a non-stretchable material.

23. A device as defined in claim 13, wherein said mask means is used in combination with an anti-wrinkling cream adapted to be applied on the skin.

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